K961150

HUDSON RCI®

SEP 10

SUMMARY OF SAFETY AND EFFECTIVENESS

March 21, 1996

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Proprietary or Trade Name: CO_2 , Oxygen Nasal Cannula

Common/Usual Name: Cannula

Intended Device: CO_2 , Oxygen Nasal Cannula

Predicate Device:

SALTER LABS Oxygen Delivery - CO_2 Sampling Nasal Cannula
K 892406 and K 863883

Device Description

The Hudson RCI nasal cannula with gas sampling port has bifurcated nares that channel oxygen delivery through both nasal prongs while allowing sampling of the patient's exhaled gas from both nasal prongs. Oxygen is delivered to the Cannula during all phases of ventilation through the base of the cannula and is directed through the lower halves of each nasal prong into the nasal pharynx. During exhalation, oxygen continues to flow into the nasal pharynx through these lower prong halves. When the gas sampling line is connected to an expiratory gas monitor, a small amount of gas is continuously withdrawn from the nasal pharynx through the upper halves of both nasal prongs. Part of this gas exits one side of the cannula and is routed via a small-bore gas sampling line to the expired gas monitor.

Intended Use

The Hudson RCI Cannula is an adjunct to oxygen therapy with its primary function being that of delivering low flow oxygen to a patient while providing a means to sample expired gas. It is intended for use in patients requiring oxygen therapy to improve blood oxygen levels while monitoring expired gas to determine ventilatory rate. No difference in intended use between the Hudson RCI and Salter Labs product has been identified.

Patient Population

The Cannula may be used on patient populations ranging from infant to adults that require low flow oxygen therapy and expired gas monitoring. No difference in patient population between the Hudson RCI and Salter Labs product has been identified.

Comparison of Technological Characteristics

The Cannula is a modification of feature and design of the SALTER LABS Oxygen Delivery/CO_2 Sampling Cannula. The main difference between the Cannula and the predicate device is that the latter delivers oxygen through one nasal prong and samples CO_2 from the other prong while the Hudson RCI Cannula will perform both functions through each nasal prong. However, the Hudson RCI Cannula and predicate device Cannula operate in a similar manner in that they each deliver a gas, usually oxygen, while providing a means to sample exhaled gas. No difference in technological characteristics between the Hudson RCI and Salter Labs product that would affect safety or effectiveness has been identified.

Conclusion

Hudson RCI has designed and manufactured the Cannula to objective criteria and believes that it is substantially equivalent to the SALTER LABS Oxygen Delivery CO_2 Sampling Cannula which has been identified as a legally marketed predicate device.